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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,033	03/22/2004	Gottfried Kellermann	3978	1008

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CLEMENTS WALKER
1901 ROXBOROUGH ROAD
SUITE 300
CHARLOTTE, NC 28211

EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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06/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,033	Applicant(s) KELLERMANN, GOTTFRIED	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blum et al. (WO 98/48785); Lang et al. (US 6,541,043) and Kumagai et al. (WO 02/100393, EP 1 393 725 is an English equivalence).

3. Blum teaches method of treatment of reward deficit syndromes (RDS), including attention deficit disorder (ADD) and attention deficit hyperactive disorder (ADHD).

See particularly pages 34-35, 43-44. The method comprises the administration to the patients an effective dose of one or more of enkephalinase inhibitors, enkephalin releasers and amino acid precursors for the dopaminergic system. 5-hydroxytryptophan, phenylalanine, glutamine, taurine and tyrosine are particularly listed as useful agents. See, particularly, pages 100-126.

Lang et al. teaches that 5-hydroxytryptophan and tyrosine are particularly useful for treatment of ADHD, especially in combination with other agent known to be useful for treatment of ADHD. See, particularly, the abstract, and the claims. Kumagai et al. teaches that theanine is particularly useful for treatment of ADHD. See, particularly, the abstract, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use 5-hydroxytryptophan, theanine, tyrosine, phenylalanine, taurine and glutamine for treatment of ADHD.

Art Unit: 1617


A person of ordinary skill in the art would have been motivated to use 5-hydroxytryptophan, theanine, tyrosine, phenylalanine, taurine and glutamine for treatment of ADHD because all the compounds are known to be useful for the treatment of ADHD. Note it is prima facie obvious to combine two or more compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; See In re Kerkhoven, 205 USPQ 1069. As to the particular schedules for administration of those known agents, note the optimization of a result effective parameter, e.g., therapeutic dosage and duration, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Since all the compounds herein are taught to be useful for treatment of ADHD, the employment of certain combination of any of those compounds for certain period of time would be within the general teaching of the prior art and is deemed to be an obvious variants of therapeutic regimen. In the instant case, Applicants attempt to capture these obvious variants of the old and well known therapeutic method. Absent an illustration of unexpected benefits residing in the specific combination and schedule herein claimed, the instant claims remain properly rejected under 35 USC 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SHENGJUN WANG
PRIMARY EXAMINER
Shengjun Wang
Primary Examiner
Art Unit 1617